Subject: Noncompliance and Human Subject Research Violations Report at UCSD
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Brief Noncompliance and Human Subject Research Violations Report at UCSD

Introduction

This report is in regards to the Human Research Protection Program at UCSD. The most serial noncompliant IRB in the UC system if not in the country for its size. Whistleblowing is not an action that is taken lightly. We, the ones voicing the frustration on behalf the HRPP staff, are well aware of what may be the consequences of our action; already retaliation against us is being met out for bringing our concerns to management and the IRB committees.

We are reaching out to whom it may concern outside of the UCSD School of Medicine because things have gotten to the point where looking the other way is not a reasonable solution. In the past, we have seen regimes come and go. The IO hires and fires IRB directors, all with the same mandate: rubber-stamp approval. We continued to perform our duties with the sentiment: "it's about outlasting them." The current regime has given us more alarm than ever for reasons that we will outline below. We feel obligated to report these matters outside of our chain of command because we have tried all available avenues and have failed to get relief. Our responsibilities are protecting human subjects in research and making sure that institutional policies and local/state/federal regulations are adhered to in that regard. We are also doing this because we love working at UCSD and believe in its primary mission. Recently we have been profiled in the local news in a negative way. Soon enough, we will start getting national attention with local and federal agencies.

What makes the UCSD HRPP more unique from all other offices of its kind in the UC system is where it is housed. While almost all HRPP offices under the UC system are under the VC for Research and Compliance, the UCSD HRPP is housed under the school of medicine to be overseen by the Director of the UC San Diego Altman Clinical and Translational Research Institute (ACTRI). “ACTRI provides infrastructure and support for basic, translational, and clinical research throughout the San Diego region; expedites the translation of discoveries into therapies; and facilitates the training and education of the next generation of researchers. We carry out our activities in collaboration with institutional and corporate partners.” Our report will be brief enough to protect our identities, and give enough information to the Chancellor’s office and UCOP to address these issues.

UCSD’s HRPP and Research Staff Making the News (not in a good way):

As you may be aware we have been in the news lately in an unflattering manner. The talk around the office is that https://inewsource.org/ had access to the UCSD IRB minutes. It is believed that this access was found by the journalists in a public setting.

In regards to Christie's Place and Kip Kantelo's action, we were left scratching our heads: Here is a case where our researchers and IRB did everything that is expected of them, but it was the Director of Research Administration who suggested not to inform the human subjects about the breach. There was no good rationale to this decision no matter how one dissects it. Of course, we know the decision was born out of the constant effort that goes on to coverup the prevalent noncompliance.

It's not the first time where someone associated with this department has been in the news regarding human subject research noncompliance issues. The New Yorker has also profiled Eric Mah once before. In regards to this noncompliance referenced in the New Yorker, UC Davis had conducted an internal audit. In the audit and in the New Yorker article, Eric and the audit itself conveniently reference the HHS's definition of research rather than the FDA's. We mention this not to relitigate the past. We are merely trying to show a pattern of misjudgment and the dereliction of duty these individuals had, and continue to, exhibit. So, throughout this report when we discuss compliance, ethics, fairness and independence, we hope you refer back to these articles as a testament to the judgment of our senior leadership.

- UCSD has not told women with HIV of data breach, despite researchers' pleas
- UCSD eye doctor broke human research rules, putting patients at risk
- 'Banished' blood, stool samples from San Diego veterans used in research article, despite federal probe
- Prominent UCSD eye doctor 'on leave' after *inewsource* investigation
- UCSD doctor resigns amid questions about undisclosed Chinese businesses
- Bacteria on the Brain
- Investigation into Allegations that Dr. Rudolph Schrot violated the Faculty Code of Conduct (publicly available)

Noncompliance issues

The items listed below are just a glimpse of the noncompliance issues that senior leadership purposefully neglects or perpetuates:

- Senior leadership pressures the IRB committees and staff to approve projects when it's evident that the projects conflict with local/state/ federal regulations, and institutional policies. [Contrary-45CFR 46, 21CFR56, California local and state laws, and UCOP policies]
- Additional or new risk information is not given to subjects as required by (45 CFR 46.109(b), 21 CFR 56.109(b)) "when in the IRB's judgment the information would meaningfully add to protection of the rights and welfare of subjects." Take a look at Christie's Place and Dr. Zhang protocols. There are many more violations of these kinds.
- The IRBs don't review Conflict of Interest Management plans of investigators who engage in human research. Both Kantelo and Mah has been aware of this for almost a year now.
- Contrary to (45 CFR 46.107(a), 21 CFR 56.107(a) it's often that members present at convened IRB meetings lack the expertise to make determinations required for approval of research. Again, this is due to senior leadership not having any interest in bringing more qualified people into the IRB.

- Contrary to (45 CFR 46.108(b), 21 CFR 56.108(b)) little substantive review takes place at convened meetings because senior leadership has no interest in recruiting more IRB members and giving them adequate time to review.
- Contrary to (21 CFR 56.108(b)) the following are not promptly reported to the IRB, appropriate institutional officials, and the Food and Drug Administration: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.
- Pressure is applied to staff and IRB committees not to fulfill the following IRB responsibilities:
    a) Risks to subjects are minimized (45 CFR 46.111(a)(1), 21 CFR 56.111(a)(1));
    b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects (45 CFR 46.111(a)(2), 21 CFR 56.111(a)(2));
    c) Selection of subjects is equitable (45 CFR 46.111(a)(3), 21 CFR 56.111(a)(3));
    d) Informed consent will be sought from each prospective subject (45 CFR 46.111(a)(4), 21 CFR 56.111(a)(4)); and,
    e) The possibility of coercion or undue influence is minimized (45 CFR 46.116, 21 CFR 50.20).
- No ongoing developmental education materials for IRB members to ensure their awareness of federal regulations and institutional policies regarding financial relationships and interests in human subject research.
- Contrary to 45 CFR 46.107(e), 21 CFR 56.107(e), senior leadership has no real interest in ensuring that members who review research have no conflicting interests.
- 21 CFR 56.109(f) gives the IRB the authority to observe, or have a third party observe, the consent process and the research. When was the last time the IRB was allowed to conduct that kind observation? We cannot tell you, but look at the above referenced news items.

Institutional Conflict:

On June 5, 2018, Kantelo was hired at UCSD as Director of Clinical Research Administration at ACTRI. He reports to Mah the Assistant Dean for Clinical & Translational Research. A couple of months after that we were informed that Kantelo was the new HRPP Interim Director. When he was first appointed, we had high hopes for him to put us in the right direction. We started seeing troubling signs after our November 28, 2018 staff meeting. In this meeting Kantelo discussed the upcoming Common Rule changes. We found the information presented to be inadequate. A PowerPoint slide was shown about how the HRPP office will change. Two alarming points were made in the slide:

- “Enshrine and incentivize flexibility”
- “To be defined: policymaking process, appeals process”

What is the meaning of “Enshrine and incentivize flexibility” in an office that deals with ethics and compliance? They are creating an atmosphere that incentivizes employees who are flexible in interpreting and applying regulations and policies that govern human research subjects and keeps investigators and the institution compliant. This was a call to compromise UCSD’s mission and our

core value.
What do they mean by “to be defined-appeals process?” The federal regulations are clear on this matter. (45 CFR 46.112, 21 CFR 56.112) State research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB. Since Kantelo has arrived here we have seen IRB committees pressured to approve studies that do not meet the Criteria for Approval (45 CFR 46.111, 21 CFR 56.111). We’ve also witnessed higherups shopping protocols to different IRBs to get approval or farming them out to commercial IRBs.

We have been informed that the HRPP office will be renamed to IRB services. One thing that bothers almost everyone on our team is when senior leadership parades those “corporate partners” – investors - through our work spaces. There is no lab on our wing of the floor. Now investigators are referred to as customers. What the above initiatives signify is the race to the bottom.

Karen Allen is the Regulatory Affairs Director for ACTRI. As Mah stated in his introduction email: "In her new role at UCSD in the ACTRI, Allen will lead our efforts to reconfigure and improve regulatory support services for our research teams, implementing our quality improvement program, and providing training opportunities." She supervises the research staff at ACTRI per her primary role. A few months ago, she started supervising the IRB staff as well. The research staff she supervises are research coordinators who submit study materials to the IRB for review. The research coordinators ultimately work for the investigators. Allen attends and fully participates in the IRB meetings. Allen doesn’t leave the room during the IRB meetings when studies her research coordinators have submitted are being deliberated and voted upon. On top of that, Allen reviews, edits, and approves the IRB's letters, which include the studies her staff has submitted. How is this O.K.?

The leadership has also started to use a concerning phrase — “we are not gatekeepers.” For example, a study one of the IRBs reviewed had a procedure that state and federal government did not allow. The leadership's guidance was that it's not the IRB's responsibility to make sure there is approval from that entity for the protocol before the IRB grants approval. This is contrary to both (45 CFR 46, 21 CFR 56).

Now, it could be argued by senior leadership that the FDA recently inspected the HRPP office and it found no serious noncompliance. However, the FDA inspector that showed up was eager to leave the moment she arrived; was given sanitized minutes to inspect; and didn’t dig nearly as deep as she could have.

If the FDA had inspected us with a road map, there would have been a very different outcome.

Professional conduct and sense of fairness

There has been shunning and wholesale retaliation toward the rank and file of the staff. As of August 9, 2019, we have not received our performance evaluations. Is this not another UC policy violation? We have notified UC San Diego Health Human Resources several times about this particular situation, but all they can tell us is that Kantelo has been sent “noncompliant" emails.

We work hard. We are a great asset to the institution and UC as a whole. In our small capacity we have tried to be the check and balance to our leadership's tendencies to ill-advised policy actions. We do so by staying in the lane of the regulatory guidance and UC policies. Some of us have moved here from the Midwest and as far as the East Coast in the hopes of better and fair work and life balance. What we found is quite the contrary. Our moral compass is consistently challenged.

In Conclusion:

Currently, UCSD has no independent IRB because it is housed under ACTRI. Essentially the fox is guarding the henhouse and things are deteriorating further. We understand that UCSD has to compete for research dollars. However, no matter how much the IRB is made to be more flexible, it alone is not going to help fill the deficit gap. What is going to happen is someone will get hurt.

In conclusion, we hope you read this report and take appropriate action. Excising the HRPP office from this situation and putting it under its rightful place, the Office of Research Compliance and Integrity, is the way to go.

We are more than happy to provide specific examples and supporting documentation behind each and every violation referenced in this complaint. However, we would like a guarantee of whistleblower protection before proceeding.

References:

- 45 CFR 46 2018 Requirements and Pre-2018 Requirements - PDF
- 21 CFR 56
- Financial Conflict of Interest: HHS Guidance (2004)
- Comparison of FDA and HHS Human Subject Protection Regulations
- Attachment: Institutional official responsibilities - draft example of guidance to be developed
- Fraud, Waste and Abuse of NIH Grant Funds